IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE BOARD OF APPEALS

APPLICANT:	Mark et al.	ATTY. DOCKET NO.:	P97,1036
SERIAL NO:	09/025,363	GROUP ART UNIT:	1616
FILED:	Febraury 18, 1998	EXAMINER:	S. Sharareh

INVENTION: "CALORICALLY DENSE NUTRITIONAL COMPOSITION"

Hon. Assistant Commissioner for Patents

Washington, D.C. 20231

APPELLANTS' APPEAL BRIEF

Sir:

Appellants submit this Appeal Brief in support of the Notice of Appeal filed on January 12, 2000 from the Final Office Action dated December 23, 1999.

I. REAL PARTY AND INTEREST

The real party in interest, as the assignee of the above-identified patent application, is Nestec S.A., by assignment recorded in the United States Patent and Trademark Office on February 18, 1998, at Reel 8984, Frame 0517, ID: 100645988A.

II. RELATED APPEALS AND INTERFERENCES

Appellants do not believe that there are any other appeals which will directly affect or be directly affected by or have a bearing on this appeal.

III. STATUS OF THE CLAIMS

Claims 1-2, 4-5, and 7-22 are pending in the patent application. A copy of the claims involved in this appeal is attached hereto as the Appendix. Claims 1-20 were rejected in a final Office Action dated September 14, 1999[1] (a copy of the final Office Action is attached hereto as Exhibit A).

IV. STATUS OF AMENDMENTS

All amendments have been entered.

V. SUMMARY OF THE INVENTION

The present invention relates generally to the treatment and nutritional support of patients. More specifically, the present invention relates to compositions for use in metabolically stressed patients who require food restrictions, but do not necessarily require increased levels of protein. (See page 1, lines 5-10.)

The traditional form of nutritional support is to administer whole protein liquid feedings to a patient to remedy protein deficiencies. However, some patients requiring nutritional support have a compromised absorptive capacity and thus cannot tolerate whole protein liquid feedings as well as the long-chain fatty acids and complex carbohydrates often present in such whole protein feedings. Many diseases or their consequences can also cause malabsorption by impairment of either digestion or absorption. As a result, semi-elemental and elemental protein diets were developed to treat such compromised patients. (See page 1, lines 19-28.)

---

[1] This Board will note that the final Office Action incorrectly notes that "Claims 1-20" are pending.

Many patients suffering from metabolic stress have a significant need for increased energy, but often do not need or can not tolerate protein levels beyond normal requirements. Such patients also cannot tolerate the food volume necessary to deliver the energy they need. As a result, such patients need an elemental diet that provides calorically dense nutritional support while at the same time providing moderate non-protein calories per gram of nitrogen. Although a variety of elemental and semi-elemental diets are currently being used in an attempt to treat and/or provide nutritional requirements to such patients, prior to the claimed invention, the inventors do not believe the needs of a metabolically stressed patient were being adequately met. (See page 2, lines 12-26.)

Accordingly, the claimed invention on appeal provides a nutritional composition designed for metabolically stressed patients. The claimed invention provides nutritional support with formulations containing increased caloric density without elevated protein levels or excess fluid. (See page 3, lines 5-9.) Specifically, the claimed invention provides calorically dense nutritional support in the form of an elemental diet while at the same time providing a moderate NPC/gN ratio (See page 6, lines 26-29).

The protein source of the claimed invention preferably comprises 15-20% of the total calories of the composition. The chosen protein source maximizes tolerance and absorption by the use of a hydrolyzed protein. This type of protein source reduces the incidence of gastric reflux because gastric emptying is faster with hydrolyzed proteins than with diets containing casein or whole whey. Also, the hydrolyzed whey protein of the claimed invention serves as a rich source of the amino acid cysteine. Cysteine is a rate limiting amino acid for the formation of glutathione; glutathione needs are greater in patients with chronic inflammatory and infectious conditions. (See page 7, lines 5-29.)

The claimed invention also includes a carbohydrate source. Carbohydrates are preferably present in an amount from 35-65% of the composition. (Page 8, lines 12-20).

Additionally, the claimed invention provides a lipid source. The lipid source includes a mixture of medium-chain triglycerides and long-chain triglycerides. The lipid source is preferably present in an amount of 20-50% of the caloric content of the composition. (See page 8, lines 21-28.)

Further, the composition of the claimed invention contains a specialized vitamin and mineral profile. The composition includes at least 100% of the United States recommended daily allowance of vitamins and minerals in 1500 k/cal. (See page 9, lines 27-29 and page 10, lines 1-5.) Moreover, the composition includes higher levels of key vitamins and minerals designed to support the metabolically stressed patients. This includes increased amounts of zinc, vitamin C, selenium, beta-carotene, and magnesium. (See page 10, lines 6-29 and page 11, lines 1-4).

The claimed composition is a ready to use enteral formulation. The composition can provide the total nutritional requirements of a metabolically stressed patient or can be used as a supplement. The composition can be fed to a patient through a tube or fed by having the patient drinking same. (See page 12, lines 22-27).

Unlike prior formulations, the claimed invention provides a calorically dense nutritional support in the form of an elemental diet while at the same time providing a moderate NPC/gN ratio. To this end, the claimed invention provides a caloric density of at least 1.4 kcal/ml. The composition also provides a moderate NPC/gN ratio of at least 90:1. Further, unlike prior formulations, the claimed invention has a low osmolality of approximately 375-600 mOsm/kg H_2O in an unflavored product and in a flavored product approximately 500-700 mOsm/kg H_2O. (See page 13, lines 3-19.)

Because of the caloric density, the composition of the claimed invention may be utilized to treat metabolically stressed patients. As used in the patent application, metabolically stressed patients are patients who, due to either a disorder or condition, are unable to tolerate whole protein diets and have fluid restrictions (they cannot tolerate excess fluid), while at the same time they cannot tolerate elevated levels of protein. (See page 13, lines 20-26.)

Examples of the claimed invention are provided on pages 15-18 of the patent application.

VI. ISSUES ON APPEAL

The following issues are on appeal:

1. Are any of Claims 1-2, 4-5, 7, 9-13, 15, or 17-20 anticipated by U.S. Patent No. 5,504,072 (*Schmidl*)?

2. Would any of Claims 1-2, 4-5, and 7-20 have been obvious to one skilled in the art at the time of the invention over *Schmidl* in view of U.S. Patent No. 5,714,472 (*Gray*)?

VII. GROUPING OF THE CLAIMS

Appellants do not argue for the patentability of the independent claims separate and apart from each other unless it is stated differently. Appellants do argue for the patentability of some of the dependent claims separate and apart from the independent claims from which they depend as noted below. The reasons supporting Appellants' position that these claims are separately patentable are provided in Section VIII (Argument) below in accordance with Rule 1.192(c)(8).

VIII. ARGUMENT

A. The Rejection

The final rejection rejects Claims 1-7, 9-13, 15, and 17-20 under 35 U.S.C. § 102(c) as allegedly being anticipated by *Schmidl*[2]. Attached hereto as Exhibit A is a copy of the final Office action; located at Exhibit B is a copy of the first Office Action that originally asserted *Schmidl*; located at Exhibit C is an Advisory Action that was submitted in response to Appellants' Response After Final; and located at Exhibit D is an Interview Summary dated January 6, 2000 that clarifies the rejections made in the final rejection and the Advisory Action. In principle part, the basis for the Examiner's rejection is as follows:

> . . . *Schmidl et al.* disclose suitable protein source including partially hydrolyzed protein (see col. 4, lines 55-59)and indicate the use of partially hydrolyzed protein or intact protein as the source of protein, not partially hydrolyzed protein and intact protein (see col. 11, lines 31-34). Further, *Schmidl's* composition provides a non-protein calorie to grams of nitrogen ratio of ranging from 150:1 to 80:1 (see col. 5 lines 64-68 and col. 6 lines 1-11). Applicant's argument that *Schmidl's* composition has caloric density of 1 Kcal/ml; not 1.4, is not impressive, because it inherently possess the claimed property. *Schmidl et al.* disclose that their composition in the powder form has the caloric density of 4 cal/gram which can easily be diluted with an aqueous liquid or juice to yield the caloric density of 1.4 kcal/ml, while maintaining an osmolality of about 630-690 mosm/kg of water (see col. 7, lines 50-59).

See Advisory Action dated December 23, 1999, page 2 at Exhibit C.

Claims 1-20 stand rejected as being unpatentable over *Schmidl* in view of U.S. Patent No. 5,714,472 (*Gray*)[3]. In part, the Examiner states as follows in support of the rejection:

> . . . *Schmidl et al.* teach the desired NPC:N ratio for critically ill patients to be in the range of 150:1 to 80:1 (see col. 5 lines 65-67 and col. 6 lines 1-3.) Further it is well known in the art that the nitrogen content of the composition can be

---

[2] Applicants note that the final rejection improperly rejects Claims 3 and 6 that have been canceled.

[3] Once again, Appellants point out that Claims 1-2, 4-5, and 7-22 are pending in this appeal, not claims 1-20.

measured to best fit the needs of critically ill patients; as indicated by *Schmidl et al.* (see col. 6 lines 2-9). Also the use of antioxidants, vitamins, and various minerals is routine in nutrition art, and further *Schmidl et al.* provide such teachings in their patent (see col. 9 lines 45-66 and col. 10 lines 1-25).

Gray et al. teach an enteral nutritional formulation that meets the nutritional needs of critically ill and metabolically stressed patients such as post-surgical patients or patients suffering from trauma in an intensive care setting, therefore, one skilled artisan would have been motivated to change the nonprotein calorie to grams of nitrogen ratio of *Gray's* composition to the desired ratio best fit for critically ill patients; as taught by *Schmidl et al.*, and modify *Gray's* composition to formulate a product that suit the needs of metabolically stressed patients.

See Advisory Action dated December 23, 1999, page 3 at Exhibit C.

B. <u>The Claims on Appeal</u>

Claims 1-2, 4-5, and 7-22 are on appeal. Of these claims, Claims 1, 9, and 17 are the independent claims. The independent claims provide as follows:

1. An enteral composition designed for metabolically stressed patients comprising:

a protein source comprising approximately 15% to 20% of the calorie distribution of the composition, the protein source consists essentially of partially hydrolyzed protein;

a carbohydrate source; and

a lipid source including a mixture of medium and long chain triglycerides, the enteral composition having a caloric density of at least 1.4 kcal/mL, wherein the composition provides a ratio of non-protein calories per gram nitrogen of about 140:1 to about 100:1.

9. A method for providing nutrition to a metabolically stressed patient comprising the step of administering to the patient a therapeutically effective amount of a composition comprising:

a protein source comprising approximately 15% to abou 20% of the calorie distribution of the composition, the protein source consists essentially of partially hydrolyzed protein;

a carbohydrate source; and

a lipid source including a mixture of medium and long chain triglycerides, the enteral composition having a caloric density of at least 1.4 kcal/mL.

17. An enteral composition for a metabolically stressed patient comprising:

about 15% to about 20% of the calorie distribution of the composition of partially hydrolyzed whey protein;

a carbohydrate source; and

a lipid source including a mixture of medium and long chain triglycerides;

the composition having a caloric density of at least 1.4 kcal/mL and a ratio of non-protein calories per gram of nitrogen of at least about 90:1.

C. *Schmidl* Does Not Anticipate Any of the Pending Claims

1. THE CORRECT LEGAL ANALYSIS FOR DETERMINING ANTICIPATION

Of course, "for a prior art reference to anticipate in terms of 35 U.S.C. § 102, every element of the claimed invention must be identically shown in the single reference." *In re Bond*, 910 F.2d 831, 15 U.S.P.Q. 2d 1566 (Fed. Cir. 1990). "There must be no difference between the claimed invention and the reference disclosure, as viewed by a person of ordinary skill in the field of the invention." *Scripps Clinic & Research Foundation v. Genetech, Inc.*, 927 F.2d 1565, 18 U.S.P.Q. 2d 1001 (Fed. Cir. 1991).

Indeed, even a generalized broad disclosure does not necessarily anticipate a claim even if the claims falls within the disclosure. "Although [a patentee's] specific claims are subsumed in a [prior art reference's] generalized disclosure. . .this is not literal identity." *Minnesota Mining and Manufacturing Co. v. Johnson & Johnson Ortopaedics Inc.*, 976 F.2d 1559, 1572, 24 U.S.P.Q. 2d 1321 1332 (Fed. Cir. 1991). In fact, "that a claimed compound may be encompassed by a disclosed generic formula does not by itself [even] render that compound obvious." *In re Baird*, 16 F.3d 380, 29 U.S.P.Q. 2d 1550 (Fed. Cir. 1994).

And of course, it is axiomatic that a reference must be considered as a whole. Portions arguing against or teaching away must be considered. *Bausch & Lomb, Inc. v. Barnes-Hind/Hydrocurve, Inc.*, 796 F.2d 443 (Fed. Cir. 1986). "A reference may be said to teach away when a person of ordinary skill, upon reading the reference, would be discouraged from following the path set out in the reference, or would be led in a direction divergent from the path that was taken be the Applicant." *In re Gurley*, 27 F.3d 551 (Fed. Cir. 1994).

2. *SCHMIDL* FAILS TO DISCLOSE A PLETHORA OF CLAIMED ELEMENTS

a. *Schmidl* fails to disclose a caloric denisty of 1.4 kcal/mL

Each of the claims on appeal is limited to an enteral composition having a caloric density of 1.4 kcal/ml. As previously noted, this is a critical issue with respect to the patient population of Appellants' claimed invention. Such patients are fluid restricted. Further, such patients have specific energy requirements.

In contrast to the claimed invention, *Schmidl* teaches a caloric density of 1 kcal/ml. Specifically, *Schmidl* states:

> The composition can also be in the form of a ready to use aqueous liquid which preferably has caloric content of about 1 kcal/ml.

See column 7, lines 54-57. Thus, if anything, *Schmidl* teaches away from the claimed invention.

The Examiner points to the sentences immediately preceding the above quoted sentence and relies on the fact that the composition of *Schmidl* can be provided in a powder form. However, in order to be administered to the patient, the composition must be diluted. *Schmidl* specifically teaches to dilute the composition to 1 kcal/ml. See, for example, column 7, lines 54-57. Thus, once again, if anything, *Schmidl* teaches away from the claimed invention.

The Examiner states that because the powder must be diluted, it inherently possesses the claimed invention. Appellants ask why? "The mere fact that a certain thing may result from a given set of circumstances is insufficient to prove anticipation." *Electro Medical Systems, S.A. v. Cooper Life Sciences, Inc.*, 34 F.3d 1048 (Fed. Cir. 1994). Inherency requires that the claimed element by necessity follows from the prior art disclosure. "A retrospective view of inherency is not a substitute for some teaching or suggestion which supports the selection and use of the various elements in the particular claimed combination." *In re Newell*, 891 F.2d 899 (Fed. Cir. 1989), *cert. denied*, 493 U.S. 814 (1989). "To establish inherency, the [reference] must make clear that the missing descriptive matter is necessarily present in the [reference]." *In re Robertson*, 169 F.3d 743 (Fed. Cir. 1999). "Inherency, however, may not be established by probabilities or possibilities. The mere fact that a certain thing may result from a given set of circumstances is not sufficient." *Id.*

Schmidl does not disclose diluting the powder to a caloric density of 1.4 kcal/mL or greater. Instead, *Schmidl's* only mention of caloric density is to state that the caloric density of the product is 1 kcal/mL; this teaches away from the claimed invention. Thus, this limitation of each of the claims is missing from *Schmidl*.

b. *Schmidl* fails to disclose the use of hydrolyzed protein.

Moreover, each independent claim requires that the protein source "consist essentially of" partially hydrolyzed protein. *Schmidl* teaches that a number of proteins can be utilized including intact protein along with protein hydrolysates. In this regard, *Schmidl* merely recites a litany of possible proteins. The protein is not an essential requirement of *Schmidl*. Thus, at best, *Schmidl* discloses a broad, generalized disclosure that the Court of Appeal for the Federal Circuit has held does not anticipate a claim even if the claim falls within the broad generalized disclosures. This is especially true when Appellants have limited claimed invention to "consisting essentially of" language.

Of course, "consisting essentially of" is a transition phrase used in patent claims to limit the claim and to signal a partially open claim. *PPG Industries v. Guardian Industries, Corp.*, 156 F.3d 1351 (Fed. Cir. 1998). The phrase excludes from the claim, ingredients that material affect the basic and novel characteristic of the claimed invention. *Atlas Powdered Company v. E.I. Dupont de Nemours Co.*, 750 F.2d 1569 (Fed. Cir. 1984). *Schmidl* specifically states with respect to the protein source:

> Suitable protein sources for the protein component can include conventional sources of intact protein, protein hydrolysates and crystalline amino acids used in enteral feeding compositions, such as, for example, casein, soy, lactalbumin, egg albumen, whey and the like.

See column 4, lines 54-59. A protein source that includes partially hydrolyzed proteins with intact proteins does not read on "consisting essentially of" partially hydrolyzed proteins.

In response to Appellants' arguments, the Examiner refers Appellants to Claim 12 of *Schmidl*. First, it is axiomatic that it is the disclosure of the prior art reference that is relevant not the claims. The prior art must disclose the claimed invention not claim it. Second, Claim 12 of *Schmidl*, that is pointed to by the Examiner, is not even in proper format. It uses alternative

language to claim the invention. In this regard, Claim 12 of *Schmidl* claims a protein component that comprises either partially hydrolyzed protein or intact protein. It is clear from the disclosure of *Schmidl* that the protein sources are irrelevant to the invention disclosed therein. The Claim 12 of *Schmidl* that is relied on by the Examiner confirms this belief. As far as *Schmidl* is concerned, intact and hydrolyzed proteins are interchangeable.

One skilled in the art reviewing *Schmidl* for what it teaches would be as likely to use intact proteins as hydrolyzed proteins. Thus, the general broad disclosure of *Schmidl* does not read on Appellants claimed invention especially in view of the fact that the claims are limited to "consisting essentially of" language.

Accordingly, Appellants respectfully submit that the anticipation rejection of the independent claims is improper and therefore should be reversed. Likewise, by definition, the dependent claims that depend from the independent claims are also not anticipated.

3. ADDITIONALLY, *SCHMIDL* FAILS TO DISCLOSE OR SUGGEST ELEMENTS OF THE DEPENDENT CLAIMS

Claims 4 and 12 require that the composition includes 100% of U.S. RDA vitamins and minerals in 1500 kcal. Even assuming *Schmidl* provides 100% of the U.S. RDA of vitamins and minerals, which is not apparent from the document nor has the Examiner pointed out where this is disclosed, the product of *Schmidl* is designed to provide such in 1800-2000 calories. In this regard, *Schmidl* states, "based on clinical experience, the compromise of achieving a 'moderate osmolality' in feeding approximately 1800-2000 mL and 1800-2000 calories per day is acceptable for the composition of the present invention." (See column 7, lines 45-49).

Accordingly, *Schmidl* does not provide 100% of U.S. RDA in 1500 calories as it is designed to provide at least 1800 calories per day. Thus, dependent Claims 4 and 12 are not anticipated by *Schmidl* for this additional reason.

Dependent Claim 5 requires that the carbohydrate source comprise 51% of the composition. *Schmidl* discloses that carbohydrates comprise 65-80% of the composition. Thus, this claim is not anticipated by *Schmidl* in addition to the reasons set forth above with respect to the independent claim.

D. Nor Are Any of the Claims Obvious in View of *Schmidl* in Further View of *Gray*

1. THE APPROPRIATE LEGAL ANALYSIS WITH RESPECT TO OBVIOUSNESS

"The obviousness standard, while easy to expound, is sometimes difficult to apply." *Uniroyal Inc. v. Rudkin-Wiley Corporation*, 837 F.2d 1044 (Fed. Cir. 1988). Of course, it is axiomatic that "obviousness may not be established using hindsight or in view of the teachings or suggestions of the inventor." *Par-Ordnance Manufacturing Inc. v. STS Importers International Inc.*, 73 F.3d 1085 (Fed. Cir. 1995).

The test is not whether or not the prior art can be modified so as to realize Appellants' claimed invention. Indeed, "the mere fact that the prior art could be so modified would not have made the modification obvious unless the prior art suggested the desirability and modification." *In re Laskowski*, 871 F.2d 115 (Fed. Cir. 1989). In this regard, "there must be some reason, suggestion, or motivation found that the prior art whereby a person of ordinary skill in the field of the invention would make the combination. The knowledge can not come from the Applicants' invention itself." *In re Oetiker*, 977 F.2d 1443 (Fed. Cir. 1992).

In determining obviousness in view of a reference, a reference must be considered as a whole. Those portions arguing against or teaching away from the claimed invention must be considered. *Bausch & Lomb Inc. v. Barnes-Hind/Hydrocurve Inc.*, 796 F.2d 443 (Fed. Cir. 1986). Indeed, nonobviousness can be demonstrated by the fact that the closest prior art reference "would likely discourage the art worker from attempting the substitution suggested by the [inventor]." *Gillette Co. v. S.C. Johnson & Son Inc.*, 919 F.2d 720 (Fed. Cir. 1990).

2. THE CITED REFERENCES FAIL TO DISCLOSE OR SUGGEST THE CLAIMED INVENTION

At the outset, Appellants note that the Patent Office incorrectly states that Claims 1-20 are rejected as being obvious. In this regard, Claims 3 and 6 have been canceled.

With respect to the remaining claims that have been rejected as being obvious, i.e., Claims 1-2, 4-5, and 7-20, Appellants noted above why these claims are not anticipated by *Schmidl*. Further, Appellants noted above why the independent claims, and therefore the dependent claims that depend therefrom are taught away from by *Schmidl*. Once again: 1) *Schmidl* teaches away from the caloric density of Appellants' claimed invention; 2) *Schmidl* teaches that intact and hydrolyzed whey protein should be used interchangeably; and 3) *Schmidl* teaches a composition that cannot be used with this patient population -- Appellants have specifically defined the metabolically stressed patients to which the claimed invention is directed as those having specific protein requirements as well as fluid restrictions.

The obviousness rejection utilizes *Schmidl* in combination with *Gray*. Appellants respectfully submit that *Gray* does not remedy the deficiencies of *Schmidl*.

First, *Gray* teaches away from the claimed invention by disclosing the use of a high protein content of at least 22% of the calories of the product. Each of the independent claims,

and therefore the dependent claims of the present invention, is limited to a protein source providing no more than 20% of the calories of the total composition. Once again, Appellants claimed invention is directed to meeting the nutritional needs of metabolically stressed patients without elevated protein levels or excess fluid. *Gray* teaches a high protein product, preferably 25% of the total calories (see column 3, lines 37-38).

Moreover, unlike the claimed invention, *Gray* teaches that the total non-protein calories per gram of nitrogen should be less than or equal to 70:1 (see column 5, lines 53-54). Claims 1-2, 4-5, 7-8, 11, and 17-20 require a NPC/gN ratio of at least 90:1. This is another claimed element that *Gray* teaches away from.

Still further, Appellants respectfully submit that it is at best a hindsight reconstruction of Appellants' claimed invention to combine *Schmidl* and *Gray* as suggested by the Examiner. Where is the motivation to reduce the protein level of *Gray* in view of *Schmidl* rather than increase the protein level of *Schmidl* in view of *Gray*. Where is the motivation not to provide non-protein calories per gram of nitrogen of less than or equal to 70:1 as suggested by *Gray* if *Schmidl* is combined with *Gray*. Where is the motivation to use the caloric density of *Gray* instead of *Schmidl*?

Appellants also question why, if the majority of the claims were previously rejected as being anticipated by *Schmidl,* see the first rejection, why does the Examiner also rely upon *Gray* to reject the same claims as being obvious? Appellants respectfully submit that this demonstrates two things: 1) the anticipation rejection of the claims based on *Schmidl* is clearly not proper; and 2) that the obviousness rejection is based on a hindsight reconstruction of the claimed invention.

Each of *Schmidl* and *Gray* specifically teaches away from key claimed elements of the claims on appeal. This demonstrates non-obviousness. Therefore, Appellants respectfully request that the obviousness rejection be reversed.

E. Dependent Claims 21-22 Have Never Been Rejected Based on Any Prior Art

Appellants note for the record, that dependent Claims 21 and 22 have not been rejected based on any prior art by the Patent Office. Claim 21 depends from Claim 1 and Claim 22 depends from Claim 9. Each of these claims requires that the protein source further comprises from about 0.1% to 2.0% free amino acid. Not only have these claims not been rejected based on the prior art, they have not even been discussed by the Patent Office with respect to the prior art.

Appellants respectfully submit that these claims are allowable over the prior art for the reasons set forth above with respect to the claims from which they depend. Appellants further submit that these claims are allowable because they add limitations that are neither disclosed nor suggested by the prior art to the claimed elements of the claims from which they depend. Accordingly, Appellants respectfully request that the Board confirm that these claims are allowable.

IX. CONCLUSION

For the foregoing reasons, Appellants respectfully request that the rejection of Claims 1-2, 4-5, and 7-20 be withdrawn as they are clearly improper as a matter of law and fact.

Respectfully submitted,

(Reg. No. 30,142)

Robert M. Barrett
HILL & SIMPSON
A Professional Corporation
85th Floor - Sears Tower
Chicago, Illinois 60606
Telephone: 312/876-0200
Attorney for Appellants

CERTIFICATE OF MAILING

I hereby certify that this correspondence is being deposited in the United States Postal Service, First Class Mail, Postage Prepaid in an envelope addressed to Assistant Commissioner for Patents, Washington, D.C. 20231 on March 10, 2000.

APPENDIX

CLAIMS ON APPEAL

1. An enteral composition designed for metabolically stressed patients comprising:

a protein source comprising approximately 15% to 20% of the calorie distribution of the composition, the protein source consists essentially of partially hydrolyzed protein;

a carbohydrate source; and

a lipid source including a mixture of medium and long chain triglycerides, the enteral composition having a caloric density of at least 1.4 kcal/mL, wherein the composition provides a ratio of non-protein calories per gram nitrogen of about 140:1 to about 100:1.

2. The enteral composition of Claim 1 wherein the lipid source comprises approximately 20% to 50% of the calorie distribution of the composition.

4. The enteral composition of Claim 1 including 100% of U.S. RDA of vitamins and minerals in approximately 1500 kcal.

5. The enteral composition of Claim 1 wherein the protein source comprises approximately 16% of the calorie distribution of the composition; the carbohydrate source comprises approximately 51% of the calorie distribution of the composition; and the lipid source comprises approximately 33% of the calorie distribution of the composition.

7. The enteral composition of Claim 1 wherein the composition includes per 1500 kcal of composition:

a zinc source providing from approximately 28.5 to 43.5 mg;

a vitamin C source providing from approximately 405 to 615 mg;

a selenium source providing from approximately 60 to 90 mg;

a taurine source providing from approximately 120 to 180 mg; and

a L-carnitine source providing from approximately 120 to 180 mg.

8. The enteral composition of Claim 1 further including a source of beta-carotene.

9. A method for providing nutrition to a metabolically stressed patient comprising the step of administering to the patient a therapeutically effective amount of a composition comprising:

a protein source comprising approximately 15% to about 20% of the calorie distribution of the composition, the protein source consists essentially of partially hydrolyzed protein;

a carbohydrate source; and

a lipid source including a mixture of medium and long chain triglycerides, the enteral composition having a caloric density of at least 1.4 kcal/mL.

10. The method of Claim 9 wherein the lipid source comprises approximately 20% to 50% of the calorie distribution of the composition.

11. The method of Claim 9 wherein the composition provides a ratio of non-protein calories per gram nitrogen of at least approximately 90:1.

12. The method of Claim 9 wherein the composition includes 100% of U.S. RDA of vitamins and minerals in approximately 1500 kcal.

13. The method of Claim 9 wherein the composition is fed through a tube to the patient.

14. The method of Claim 9 wherein the composition contains approximately 0.37% of the calories as cysteine.

15. The method of Claim 9 wherein the composition includes per 1500 kcal of composition:

a zinc source providing from approximately 28.5 to 43.5 mg;

a vitamin C source providing from approximately 405 to 615 mg;

a selenium source providing from approximately 60 to 90 mg;

a taurine source providing from approximately 120 to 180 mg; and

a L-carnitine source providing from approximately 120 to 180 mg.

16. The method of Claim 9 wherein the composition further includes a source of beta-carotene.

17. An enteral composition for a metabolically stressed patient comprising:

about 15% to about 20% of the calorie distribution of the composition of partially hydrolyzed whey protein;

a carbohydrate source; and

a lipid source including a mixture of medium and long chain triglycerides;

the composition having a caloric density of at least 1.4 kcal/mL and a ratio of non-protein calories per gram of nitrogen of at least about 90:1.

18. The enteral composition of Claim 17 wherein the carbohydrate source provides about 35% to about 65% of calories and the lipid source provides about 20% to about 50% of calories.

19. The enteral composition of Claim 17 which includes, per 1500 kcal:

a zinc source providing from about 28.5 to about 43.5 mg zinc;

a vitamin C source providing about 405 to 615 mg vitamin C;

a selenium source providing about 60 to about 90 mg selenium;

a taurine source providing about 120 to about 180 mg taurine; and

a L-carnitine source providing about 120 to about 180 mg L-carnitine.

20. The enteral composition of Claim 17 which has a caloric density of about 1.4 to about 1.8 kcal/mL.

21. The enteral composition of Claim 1 wherein the protein source further comprises from about 0.1% to 2.0% free amino acids.

22. The method of Claim 9 wherein the protein source further comprises from about 0.1% to 2.0% free amino acids.

SUPPLEMENTAL APPENDIX

Copy of final Office Action dated September 14, 1999 ..... Exhibit A

Copy of first Office Action dated April 28, 1999 ..... Exhibit B

Copy of Advisory Action dated December 23, 1999 ..... Exhibit C

Copy of Interview Summary dated January 6, 2000 ..... Exhibit D

Exhibit A

UNITED STATES DEPARTMENT OF COMMERCE
Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231

H.B.

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/025,363	02/18/98	MARK D	P97.1036

HM12/0914

HILL & SIMPSON
85TH FLOOR SEARS TOWER
233 SOUTH WACKER DRIVE
CHICAGO IL 60606

EXAMINER	
SHARAREH, S	

ART UNIT	PAPER NUMBER
1616	6

DATE MAILED: 09/14/99

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Tradema

Office Action Summary	Application No. 09/025,363	Applicant(s) David Mark et al
	Examiner Shahnam Sharareh	Group Art Unit 1616

☒ Responsive to communication(s) filed on *2/18/98, and 7/19/99*

☒ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire *3* month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) *1-20* is/are pending in the application.

Of the above, claim(s) _____ is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) *1-20* is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐approved ☐disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____.

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☐ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

DETAILED ACTION

Response to Applicants Arguments for Claim Rejections - 35 USC § 102

Applicant's arguments and the newly amended claims filed on 7/19/99 have been fully considered but they are not found to be persuasive.

In contrary to Applicant's assertion that Schmidl et al does not anticipate the claimed invention, Examiner responds that Schmidl et al clearly disclose compositions comprising a protein component providing 16-25% of the total calorie of the formula, a lipid and a carbohydrate source wherein the protein content further comprise partially hydrolyzed protein.

Since the terms "Calorie", "Calories" or "Kilocalories" have been interchangeably used in the art, Schmidl's composition inherently possesses a caloric density of one Kilocalorie per milliliter. In addition, when a patent contains a range that varies from the parameter in a prior art, "the applicant must show that the particular range is critical, generally by showing that the claimed range achieves unexpected results relative to the prior art range." *Woodruff, 919 F.2d 1578 [16 USPQ2d 1934] see also* In re Ornitz, *351 F.2d 1013 [147 USPQ 283] (C.C.P.A. 1965).* It is also well-established that merely selecting proportions and ranges is not patentable absent a showing of criticality. *In re Becket, 33 USPQ. 33 (C.C.P.A. 1937).* In re Russell *439 F.2nd 1228, 169 U.S.P.Q. 426 (C.C.P.A. 1971).* Therefore, Examiner adheres to the rejection that was made in the Office Action 4/28/99, because Schmidl et al disclose an enteral formulation comprising a protein source that can provide approximately 16-25% of the calorie distribution of

the formulation, wherein said protein source comprise a protein hydrolysate such as whey hydrolysate or alike (see Col 4 lines 51-67), a carbohydrate source, a lipid source including medium and long chain triglycerides, a Zinc source, a Selenium source, a Taurine source, a Cysteine source, a L-Carnitine source, a Vitamin C source (see Col 4 lines 1-51 and Col 8 table), and wherein said formulation provides a non-protein calorie to grams of nitrogen ratio of ranging from 150:1 to 80:1 (see Col 5 lines 64-68 and Col 6 lines 1-11). Schmidl et al further disclose a method for administering said formulation to a patient via various tube-feeding techniques (see Col 7 lines 60-67).

Therefore, for the above stated reasons, said claims are properly rejected under 35 U.S.C § 102, and therefore, the rejection is adhered to.

Response to Applicants Arguments for Claim Rejections - 35 USC § 103

Applicant's arguments and the newly amended claims filed on 7/19/99 have been fully considered but they are not found to be persuasive. In response to applicant's argument that the Patent Office " cannot pick and choose among the individual elements of assorted prior art references to create the claimed invention" and "the prior art must suggest the desirability of a modification", Examiner replies that the test for obviousness is not whether the features of a secondary reference may be bodily incorporated into the structure of the primary reference; nor is it that the claimed invention must be expressly suggested in any one or all of the references. Rather, the test is what the combined teachings of the references would have suggested to those of ordinary skill in the art. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981). In the

instant case, Granger et al clearly discuss the advantages of using hydrolyzed protein sources in hypermetobolic patients; further, Schmidl et al disclose an enteral composition comprising suitable sources as well as concentrations of protein, lipid and carbohydrate for treating stressed and catabolic patients. In addition, the fact that the examiner has combined an excessive number of references, reliance on a large number of references in a rejection does not, without more, weigh against the obviousness of the claimed invention. See *In re Gorman*, 933 F.2d 982, 18 USPQ2d 1885 (Fed. Cir. 1991). Contrarily, the abundance of various reference; in this case, the teachings of Cope et al '872 and Gray et al, would motivate one ordinary skilled in art to best determine what combination of nutritional elements could optimize an already marketed product such as Traumacal to suit the needs of metabolically stressed patients. Additionally, the Traumacal brochure and Schmidl et al indicate the adequate range of non-protein calories per gram nitrogen ratio for various hypermetabolic states (Traumacal brochure p. 36 B00143, last paragraph, and US Patent 5,504,072 see col 4 lines 1-5.); as do Gray et al '472 and Cope et al '872 the desired caloric content of a preffered formulation (see US Patent 5,714,472 col 3 lines 49-52, and US Patent 5,480,872 col 5 lines 15-18.)

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schmidl et al US Patent 5,504,072 and Gray et al 5,714,472 for the reasons set forth in the Office Action mailed 4/28/99.

Although the protein content of Gray's formulation does not provide 15 to 20 percent of its total calories, for the same reasons set forth in the Office Action mailed 4/28/99, one skilled in the art would have been motivated, from the teachings of Schmidl, to optimize the enteral formulation of Gray et al to meet the protein requirements of metabolically stressed patients without elevated protein levels or excess fluid.

For the above stated reasons, said claims are properly rejected under 35 U.S.C § 103, and therefore, the rejections are adhered to.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Dr. Sharareh whose telephone number is (703) 306-5400. The examiner can normally be reached on Monday to Friday from 8:30 a.m. to 5:00 p.m. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mr. Jose Dees can be reached on 703-308-4628. The fax phone number for this Group is 703-308-4556. Any inquiry of a general nature of relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is 703-308-1235.

sjs 8/20/99

JOSE G. DEES
SUPERVISORY PATENT EXAMINER

1616

Exhibit B

UNITED STATES DEPARTMENT OF COMMERCE
Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/025,362	02/18/98	MARK D	P97.1036

EXAMINER	
SHABAREH, S	
ART UNIT	**PAPER NUMBER**
1616	4

HM12/0428

HILL & SIMPSON
85TH FLOOR SEARS TOWER
233 SOUTH WACKER DRIVE
CHICAGO IL 60606

DATE MAILED: 04/28/99

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.	Applicant(s)
09/025,363	David Mark et al
Examiner	**Group Art Unit**
Shahnam Sharareh	1616

☒ Responsive to communication(s) filed on *Feb 18, 1998* .

☐ This action is **FINAL.**

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire *3* month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) *1-20* is/are pending in the application.

Of the above, claim(s) _____ is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) *1-20* is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐approved ☐disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____ .

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____ .

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☒ Notice of References Cited, PTO-892

☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). *2 & 3*

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

DETAILED ACTION

Double Patenting

1. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321© may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-20 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-30 of U.S. Patent 5,661,123. The instant claims are drawn to an enteral composition and a method of providing it to the metabolically stressed patients wherein said composition comprising a caloric density of about 1.4 Kcal/ml, a protein

source, a carbohydrate source, a lipid source including a mixture of medium and long chain density triglycerides, a Zinc source, a Vitamin C source, a Selenium source, a Taurine source, a L-Carnitine source, and a beta-carotene source. Although the conflicting claims are not identical and introduce different use and various different concentrations of the ingredients, but they are not patentably distinct from the patented claims, because they fail to add a distinctive limitation to the claims of U.S. Patent 5,661,123.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claim 4 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite and vague for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The phrase "100% of U.S. RDA" fails to teach and specify which nutrients meet the U.S. RDA.

Claim Rejections - 35 USC § 102

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claims 1-7, 9-13, 15, 17-20 are rejected under 35 U.S.C. 102(b) as being anticipated by Schmidl et al US Patent 5,504,072.

The instant claims are drawn to an enteral composition comprising a protein source, a carbohydrate source, a lipid source including a mixture of medium and long chain density triglycerides, a Zinc source, a Vitamin C source, a Selenium source, a Taurine source, and a L-

Carnitine source, wherein the composition provides a ratio of non-protein calories per gram nitrogen of at least approximately 90:1. Further the instant claims encompass methods of providing said composition to a patient comprising administration of therapeutically effective amount to the patient wherein said composition is fed through a tube. Schmidl et al disclose an enteral nutritional formulation that meets the nutritional needs of critically ill and metabolically stressed patients such as patients suffering from trauma, burn, malnutrition, sepsis, cancer, AIDS or other like conditions (see Col 3, lines 34-42). Schmidl et al also disclose an enteral formulation comprising a protein source that can provide approximately 16-25% of the calorie distribution of the composition that can include protein hydrolysate such as whey hydrolysate or alike (see Col 4 lines 51-67), a carbohydrate source, a lipid source including medium and long chain triglycerides, a Zinc source, a Selenium source, a Taurine source, a Cysteine source, a L-Carnitine source, a Vitamin C source (see Col 4 lines 1-51 and Col 8 table), and wherein said formulation provides a non-protein calorie to grams of nitrogen ratio of ranging from 150:1 to 80:1 (see Col 5 lines 64-68 and Col 6 lines 1-11). Schmidl et al further disclose a method for administering said formulation to a patient via various tube-feeding techniques (see Col 7 lines 60-67). Therefore, the nutritional formula of Schmidl et al meets the limitation set forth in the instant claim.

5. Claims 1-20 are rejected under 35 U.S.C. 102(b) as being anticipated by Cope et al US Patent 5,480,872. The instant claims are drawn to an enteral composition with caloric density of approximately 1.4 Kcal/ml and comprising a protein source comprising approximately 15-21% of the calorie distribution, a carbohydrate source, a lipid source including a mixture of medium and

long chain density triglycerides, a Zinc source, a Vitamin C source, a Selenium source, a Taurine source, a L-Carnitine source, and a beta-carotene source. Further the instant claims encompass methods of providing said composition to a patient comprising administration of therapeutically effective amount to the patient, wherein the protein source consists essentially of partially hydrolyzed whey proteins. Cope et al disclose a high protein, calorically dense (see col 5, lines 8-22) nutritional product for hypermetabolic patients comprising a hydrolyzed protein comprising any suitable source such as whey protein (see Col 9 line 20-46, and 1-12), a source of carbohydrate, a mixture of medium and long chain triglycerides and fatty acids, and other micronutrient such that the said nutritional product meets 100% US RDA's recommendations of all micronutrients contained (see tables 1, 2,5,6). Cope et al also disclose that the said nutritional product can be used both as an oral supplement and for enteral support, administered either orally or by tube feeding (see Col 13, lines 46-51). Since Cope et al disclose an enteral formula comprising a protein source that can contain 19-21% of the calorie distribution of the composition, a lipid source, a protein source, and other micronutrient such that the said nutritional product meets 100% of US RDA's recommendation for contained nutrients, as well as a method for administration; which are within the scope of the instant claims, said claims are anticipated by Cope et al.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371© of this title before the invention thereof by the applicant for patent.

6. Claims 1-20 are rejected under 35 U.S.C. 102(e) as being anticipated by Gray et al US Patent 5,714,472.

The instant claims are drawn to an enteral composition with caloric density of about 1.4 Kcal/ml comprising a protein source, a carbohydrate source, a lipid source including a mixture of medium and long chain density triglycerides, a Zinc source, a Vitamin C source, a Selenium source, a Taurine source, a L-Carnitine source, and a beta-carotene source. Further the instant claims encompass methods of providing said composition to a patient comprising administration of therapeutically effective amount to the patient. Gray et al teach an enteral nutritional formulation that meets the nutritional needs of critically ill and metabolically stressed patients such as post-surgical patients or patients suffering from trauma, burn or related complications. Said enteral formulation having a caloric density of at least 1.3 Kcal/ml comprising a protein source including protein hydrolysate comprising whey hydrolysate, a carbohydrate source, a lipid source including medium and long chain triglycerides, a Zinc source, a Selenium source, a Taurine source, a Cysteine source, a L-Carnitine source, and a Vitamin C source, wherein said formulation meets the U.S. RDAs recommendations of said nutrients (See col 5 lines 25-38, 65-68, and Col 6 lines 35-42, and Col 7, lines 0-14). Gray et al also disclose a method for providing said formulation to a patient comprising a step of enterally administering to the patient a therapeutically effective amount (see Col 9 and 10, all claims). Therefore, Gray et al's nutritional formula meets the limitation set forth in the instant claim.

6. Claims 1-3, 5, 7-16 are rejected under 35 U.S.C. 102(e) as being anticipated by Cope et al US Patent 5,700,782. The instant claims are drawn to an enteral composition with caloric density of approximately 1.4 Kcal/ml and comprising a protein source comprising approximately 15-21% of the calorie distribution, a carbohydrate source, a lipid source including a mixture of

medium and long chain density triglycerides, a Zinc source, a Vitamin C source, a Selenium source, a Taurine source, a L-Carnitine source, and a beta-carotene source. Further the instant claims encompass methods of providing said composition to a patient comprising administration of therapeutically effective amount to the patient. Cope et al disclose an enteral nutritional product with the caloric density of about 1.2 to 1.5 Kcal/ml comprising a protein source , a carbohydrate source (see col 9, lines 15-55) , a lipid source including a mixture of medium and long chain density triglycerides (see col 3 lines 49-66, and table 4), a Zinc source, a Vitamin C source, a Selenium source, a Taurine source, a L-Carnitine source, a beta-carotene source, and other micronutrient that may be incorporated in the enteral product (see tables 2,3,4,5). Cope et al further disclose the method of providing said enteral or nutritional product to a patient (see col 5, lines 46-56, col 10, lines 13-53). Therefore Cope discloses a nutritional product that meets the limitation set forth in the instant claim.

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

8. Claims 1-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over TRAUMACAL ™ (Mead Johnson, Document bearing No B00107-180), Trimbo et al US Patent 5,166,189, Stalker et al US Patent 5,661,123, as applied to claim 1-20 above, and in view of Schmidl et al US Patent 5,504,072, Cope et al US Patent 5,480,872, Gray et al US Patent

5,714,472, Cope et al US Patent 5,700,782, Maubois et al US Patent 4427658, and Granger et al (JPEN 12:278-281,1988).

The instant claims are drawn to an enteral composition with caloric density of approximately 1.4 Kcal/ml and comprising a protein source, a carbohydrate source, a lipid source including a mixture of medium and long chain density triglycerides, a Zinc source, a Vitamin C source, a Selenium source, a Taurine source, a L-Carnitine source, and a beta-carotene source. Further the instant claims encompass methods of providing said composition to a patient comprising administration of therapeutically effective amount to the patient.

The TRAUMACAL ™ Document bearing B00107-180 disclose that the use of a high protein-caloric density formula such as TRAUMACAL ™ provides a positive Nitrogen balance, and meets the nutritional needs of metabolically stressed patients specially when using a composition having a lower Non protein calories per nitrogen (pages 36 or B00143 last two paragraphs, 43 or B00149 last paragraph , 48 or B00154 last three paragraphs, 59 or B00165 last two paragraphs). The TRAUMACAL ™ Document bearing B00107-180, however, fails to incorporate a source of hydrolyzed whey protein in its formulation.

Trimbo et al teach the method of feeding patients with pulmonary disease by administering to a patient an enteral nutritional composition comprising a total calories not less than about 18% protein, about 20-50% carbohydrate, about 40-55% lipids comprising of a mixture of medium and long chain triglycerides, that meets US RDAs recommendations of all vitamins and minerals. Trimbo et al however fails to show the use of hydrolyzed whey protein and their production by

using pancreatic enzymes. Trimbo also fails to address the use of said enteral nutritional composition in metabolically stressed patients (see entire patent).

Stalker et al teach a method of providing a enteral nutritional formulation that meets the nutritional needs of malabsorbing patients comprising a caloric density of about 1.0 Kcal/ml comprising a protein source including protein hydrolysate comprising whey hydrolysate, a carbohydrate source, a lipid source including medium and long chain triglycerides, a Zinc source, a Selenium source, a Taurine source, a Cysteine source, a L-Carnitine source, and a Vitamin C source that meets U.S. RDAs recommendations of contained nutrients. Stalker et al teach a method for providing said formulation to a patient comprising the step of enterally administering to the patient a therapeutically effective amount (See entire patent). Stalker et al fail to address the usage of said formulation for metabolically stressed patients.

Schmidl et al teach an enteral nutritional formulation that meets the nutritional needs of critically ill and metabolically stressed patients such as patients suffering from trauma, burn, malnutrition, sepsis, cancer, AIDS or other like conditions (see Col 3, lines 34-42). Schmidl et al disclose an enteral formulation comprising a protein source that can provide approximately 16-25% of the calorie distribution of the composition that can include protein hydrolysate such as whey hydrolysate or alike (see Col 4 lines 51-67), a carbohydrate source, a lipid source including medium and long chain triglycerides, a Zinc source, a Selenium source, a Taurine source, a Cysteine source, a L-Carnitine source, a Vitamin C source (see Col 4 lines 1-51 and Col 8 table), and wherein said formulation provides a non-protein calorie to grams of nitrogen ratio of ranging from 150:1 to 80:1 (see Col 5 lines 64-68 and Col 6 lines 1-11). Schmidl et al also disclose a

method for providing said formulation to a patient comprising the step of enterally administering to the patient a therapeutically effective amount (see Col 7 lines60-67). However, Schmidl et al fail to incorporate beta-carotene and L-cystine to their enteral formula.

Cope et al US Patent 5,480,872 disclose a high protein, calorically dense (see col 5, lines 8-22) nutritional product for hypermetabolic patients comprising a hydrolyzed protein comprising any suitable source such as whey protein (see Col 9 line 20-46, and 1-12), a source of carbohydrate, a mixture of medium and long chain triglycerides and fatty acids, and other micronutrient such that the said nutritional product meets 100% US RDA's recommendations of all micronutrients contained (see tables 1, 2,5,6). Cope et al also disclose that the said nutritional product can be used both as an oral supplement and for enteral support, administered either orally or by tube feeding (see Col 13, lines 46-51). Cope's teachings along with the conversion factors that are known in the art (1gm carbohydrate=3.4Kcal, 1gm protein=4.0Kcal, 1gm Fat=9.0Kcal, and 1gm N=6.25g protein)enable one skilled in the art to formulate an enteral formula comprising a protein source comprising about 18-21% of the calorie distribution of the composition when admixing about 200g of carbohydrate source, about 24.5g of a lipid source, and about 60g of a protein source, while maintaining a caloric density of about 1.4 Kcal/ml, and Non-protein calorie per Nitrogen ratio of about 90:1.

Cope et al US Patent 5,700,782 disclose an enteral nutritional product with the caloric density of about 1.2 to 1.5 Kcal/ml comprising a protein source , a carbohydrate source (see col 9, lines 15-55) , a lipid source including a mixture of medium and long chain density triglycerides (see col 3 lines 49-66, and table 4), a Zinc source, a Vitamin C source, a Selenium source, a

Taurine source, a L-Carnitine source, a beta-carotene source, and other micronutrient that may be incorporated in the enteral product (see tables 2,3,4,5). Cope et al further disclose the method of providing said enteral or nutritional product to a patient (see col 5, lines 46-56, col 10, lines 13-53). According to the Cope's disclosure and the conversion factors known in the art (1gm carbohydrate=3.5Kcal, 1gm protein=4.0Kcal, 1gm Fat=9.0Kcal, and 1gm N=6.25g protein), an ordinary skilled artisan is able to formulate a liter of an enteral formula comprising a protein source comprising approximately 17-21% of the calorie distribution of the composition when admixing about 183g of carbohydrate source, about 38.5g of a lipid source, about 64g of a protein source, while maintaining a caloric density of about 1.3 Kcal/ml, and Non-protein calorie per Nitrogen ratio of about 92:1.

Gray et al teach an enteral nutritional formulation that meets the nutritional needs of critically ill and metabolically stressed patients such as post-surgical patients or patients suffering from trauma, burn or related complications. Said enteral formulation having a caloric density of at least 1.3 Kcal/ml comprising a protein source including protein hydrolysate comprising whey hydrolysate, a carbohydrate source, a lipid source including medium and long chain triglycerides, a Zinc source, a Selenium source, a Taurine source, a Cysteine source, a L-Carnitine source, and a Vitamin C source that meets U.S. RDAs recommendations of said nutrients (See col 5 lines 25-38, 65-68, and Col 6 lines 35-42, and Col 7, lines 0-14). Gray et al also disclose a method for providing said formulation to a patient comprising the step of enterally administering to the patient a therapeutically effective amount (Col 9 and 10).

Maubois et al disclose a method of obtaining hydrolyzed whey protein as well as an enteral nutritional formulation for use in an intesive care setting to the patients who may require a protein intake of the 7-25% of total caloric intake, wherein said protein comprising a hydrolyzed whey protein (see example 5 and 6). Maubois et al fail to specifically address the U.S. RDA's nutritional needs of metabolically stressed patients.

It is well-established that merely selecting proportions and ranges is not patentable absent a showing of criticality. In re Becket, 33 USPQ. 33 (C.C.P.A. 1937). In re Russell 439 F.2nd 1228, 169 U.S.P.Q. 426 (C.C.P.A. 1971). Further it is shown in the art that hypermetabolicly stressed patients may suffer from gastrointestinal malabsorption due to the changes of the intestinal mucosa and the intestinal capillary bed; subsequently, said patients experience enhanced protein absorption when a suitable hydrolyzed protein source (such as whey, because of its well balanced aminoacids content) is used (Granger et al, Page 280-281, see discussion). Therefore, it would have been obvious to one of ordinary skill in the art to use the teachings of Gray et al or Cope et al or Stalker and Maubois and further modify the TRAUMACAL ™ formulation (ex. using hydrolyzed whey protein) to provide an improved enteral product that meets the specific nutritional requirements of metabolically stressed patients. Similarly, it would have been obvious to one of ordinary skill in the art to utilize the teachings of Schmidl et al, Trimbo and Maubois to further modify TRAUMACAL ™ formulation to provide an improved enteral product that meets the specific nutritional requirements of metabolically stressed patients. In addition, it would have also been obvious to one of ordinary skill in the art to use the teachings of Schmidl et al and further modify the nutritional formulation of Cope et al US Patent 5480872 to provide an

improved enteral product that meets the specific nutritional requirements of metabolically stressed patients.

9. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Cope et al US Patent 5,547,927, 8/20/1996, also disclose an enteral nutritional product comprising a whey protein source, a lipid source, and a carbohydrate.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Dr. Sharareh whose telephone number is (703) 306-5400. The examiner can normally be reached on Monday to Friday from 8:30 a.m. to 5:00 p.m. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mr. Jose Dees can be reached on 703-308-4628. The fax phone number for this Group is 703-308-4556. Any inquiry of a general nature of relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is 703-308-1235.

Shahnam Sharareh, PharmD

JOSE G. DEES
SUPERVISORY PATENT EXAMINER
1616

37 CFR 1.501
INFORMATION DISCLOSURE STATEMENT
IN A PATENT
(use several sheets if necessary)

Docket No. P97,1036	Serial No. 09/025,363
Applicant Mark et al.	
Filing Date February 18, 1998	Group Art Unit ~~1801~~ 1616

U.S. PATENT DOCUMENTS

Examiner's Initials		Document Number	Date	Name	Class	Subclass	Filing Date If appropriate
	AA	4,358,465	11/09/82	Brule et al.			
	AB	4,361,587	11/30/82	Brule et al.			
	AC	4,427,658	01/24/84	Maubois et al.			
	AD	4,495,176	01/22/85	Brule et al.			
	AE	4,670,268	06/02/87	Mahmoud			
	AF	4,740,462	04/26/88	Brule et al.			
	AG	4,753,963	06/28/88	Jandacek et al.			
	AH	4,816,398	03/28/89	Brule et al.			
	AI	4,920,098	04/24/90	Cotter et al.			
	AJ	4,931,300	06/05/90	Monte			
	AK	4,980,450	12/25/90	Brule et al.			
	AL	5,028,589	07/02/91	Brule et al.			
	AM	5,053,387	10/01/91	Alexander			
	AN	5,055,446	10/08/91	Alexander et al.			
	AO	5,156,875	10/20/92	Monte			
	AP	5,166,189	11/24/92	Trimbo et al.			
	AQ	5,221,668	06/22/93	Henningfield et al.			
	AR	5,223,285	06/29/93	DeMichele et al.			
	AS	5,260,279	11/09/93	Greenberg			
	AT	5,422,127	06/06/95	Dube et al.			
	AU	5,438,042	08/01/95	Schmidl et al.			
	AV	5,661,123	08/26/97	Stalker et al.			
	AW	5,714,472	02/03/98	Gray et al.			
	AX	5,723,446	03/03/98	Gray et al.			

FOREIGN PATENT DOCUMENTS

		Document Number	Date	Country	Class	Subclass	Translation Yes	Translation No
	AY	0 189 160	07/30/86	Europe				
	AZ							

Examiner SSL Date Considered 4/12/99

***EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.**

37 CFR 1.501
INFORMATION DISCLOSURE STATEMENT
IN A PATENT
(use several sheets if necessary)

Docket No. P97,1036	Serial No. 09/025,363
Applicant Mark et al.	
Filing Date February 18, 1998	Group Art Unit ~~1801~~ 1616

OTHER ART (Including Author, Title, Date, Pertinent Pages, Etc.)

✓	BA	Clintec Nutrition Company, *Proper Nutrition For ICU Patients Is Critical,* Brochure, 1994.
✓	BB	Clintec Nutrition Company, *When You Create Such A Unique Enteral Formula, It's Hard Not To Create Attention*, Brochure, 1994.
✓	BC	Clintec Nutrition Company, *Crucial Needs Require A Curcial™ Solution*, Brochure, 1994.
✓	BD	Clintec Nutrition Company, *Crucial™ Compared To Perative®*, Brochure, 1995.
inappropriate	~~BE~~	~~Clintec Nutrition Company, *When Your First Choice Has To Be Your Best Choice,*~~ Reabilan® Brochure (Undated).
no date (A1)	~~BF~~	~~Clintec Nutrition Company, *Reabilan HN*, Brochure (Undated).~~
✓	BG	Ross Laboratories Brochure, *Specialized Elemental Nutrition With Glutamine - The Role of ALITRAQ™ Specialized Elemental Nutrition With Glutamine*, 1991.
✓	BH	Ross Laboratories Brochure, *Introducing ALITRAQ™ Specialized Elemental Nutrition With Gluamine*, 1992.
✓	BI	Ross Laboratories Brochure, *Introducing PERATIVE™*, 1992.
✓	BJ	Sandoz Nutrition Brochure, *IMPACT®*, 1993.
✓	BK	Sandoz Nutrition Brochure, *INTRODUCING IMPACT®*, 1989.
✓	BL	Sandoz Nutrition Brochure, *IMPACT®*, 1991.
	BM	Mead Johnson, *Enteral Nutritionals Product Handbook*, bearing Nos. A2688-2693.
no date (S1)	~~BN~~	~~Mead Johnson Enteral Nutritionals Brochure bearing Nos. B00083.~~
	~~BO~~	~~Mead Johnson Brochure bearing Nos. B00322-B00323.~~
✓	BP	Mead Johnson, *Metabolic and Nutrition Support for Trauma and Burn Patients A Symposium*, Abstracts, 1982, pp. 1-13.
✓	BQ	*Nutritional Care of Metabolically Stressed Patients*, Proceedings from the Metabolic and Nutrition Support for Trauma and Burn Patients Symposium, White Sulphur Springs, West Virginia, 1983, pp. 1-77.
✓	BR	*Principles of Nutritional Support: Proceedings From the Metabolic and Nutrition Support for Trauma and Burn Patients Symposium*, White Sulphur Springs, West Virginia, 1982, pp. 1-25.
✓	BS	*Symposium Highlights Metabolic and Nutrition Support for Trauma and Burn Patients*, White Sulphur Springs, West Virginia, 1982, pp. 1-26.
✓	BT	*TraumaCal, Feeding the Hypermetabolic Patient, Clinical Experience, A Symposium*, 1983, pp. 1-74.
inappropriate No date	~~BU~~	~~TraumaCal Product Cards bearing Nos. B000001-10.~~
No date (S3)	~~BV~~	~~TraumaCal Documents bearing Nos. B00088-105.~~

Examiner	Date Considered
[signature]	4/12/99

***EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.**

37 CFR 1.501
INFORMATION DISCLOSURE STATEMENT
IN A PATENT
(use several sheets if necessary)

Docket No. P97,1036	Serial No. 09/025,363
Applicant Mark et al.	
Filing Date February 18, 1998	Group Art Unit ~~1801~~ 1616

OTHER ART (Including Author, Title, Date, Pertinent Pages, Etc.)

✓	CA	TraumaCal Document bearing No. B00181. 1983
	CB	~~TraumaCal Document bearing Nos. B00261-265.~~
✓	CC	TraumaCal Document bearing No. B00293. 1982
✓	CD	TraumaCal Document bearing Nos. B00384-385. 1982
	CE	~~TraumaCal Label bearing No. B00441.~~
✓	CF	TraumaCal Brochure bearing Nos. B00567-570. 1988
✓	CG	National Research Council, "Recommended Dietary Allowances, 10th Edition," Washington, D.C.: National Academy Press 1989.
✓	CH	Joint FAO/WHO Ad Hoc Expert Committee, "Protein and Energy Requirements: a joint FAO/WHO Memorandum," *Bulletin of the World Health Organization*, Vol. 57, 1979, pp. 65-79.
✓	CI	Bell et al., "Alternative lipid sources for enteral and parenteral nutrition: Long- and medium-chain triglycerides, structured triglycerides, and fish oils", *Journal of the American Dietetic Association*, Vol. 91, No. 1, 1991, pp. 74-78.
✓	CJ	Bjerve et al., "Alpha-linolenic acid deficiency in man: effect of ethyl linolenate on plasma and erythrocyte fatty acid composition and biosynthesis of prostanoids", *Am J Clin Nutr*, Vol. 46, 1987, pp. 570-576.
✓	CK	Borum, "Role of Carnitine in Lipid Metabolism", *Lipids in Modern Nutrition*, New York: Raven Press, 1987, pp. 51-58.
✓	CL	Borum et al., "Carnitine content of liquid formulas and special diets", *Am J Clin Nutr*, Vol. 32, 1979, pp. 2272-2276.
✓	CM	Chernoff et al., "The effect of a very high-protein liquid formula (Replete®) on decubitus ulcer healing in long-term tube-fed institutionalized patients", *J Am Diet Assoc.*, Vol. 90, 1991.
✓	CN	Geggel et al., "Nutritional Requirement for Taurine in Patients Receiving Long-Term Parenteral Nutrition", *The New England Journal of Medicine*, Vol. 312, No. 3, 1985, pp. 142-146.
✓	CO	Greenberger et al., "Medium-Chain Triglycerides: Physiologic Considerations and Clinical Implications", *The New England Journal of Medicine*, Vol. 280, No. 19, 1969, pp. 1045-1058.
✓	CP	Hayes, "Vitamin-Like Molecules (D) Taurine", *Modern Nutrition in Health and Disease, 7th Edition*, Philadelphia: Lea and Febiger, 1988, pp. 464-470.
✓	CQ	Heymsfield et al., "Respiratory, cardiovascular, and metabolic effects of enteral hyperalimentation: influence of formula dose and composition", *The American Journal of Clinical Nutrition*, Vol. 40, 1984, pp. 116-130.
	CR	

Examiner	Date Considered 4/12/99

***EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.**

37 CFR 1.501
INFORMATION DISCLOSURE STATEMENT
IN A PATENT
(use several sheets if necessary)

Docket No. P97,1036	Serial No. 09/025,363
Applicant Mark et al.	
Filing Date February 18, 1998	Group Art Unit ~~1801~~ 1616

OTHER ART (Including Author, Title, Date, Pertinent Pages, Etc.)

	DA	Holman, "Function and Biologic Activities of Essential Fatty Acids in Man", *Fat Emulsion in Parenteral Nutrition*, Chicago: American Medical Association, 1976, pp. 5-14.
	DB	Holt, "Medium Chain Triglycerides: A Useful Adjunct in Nutritional Therapy", *Gastroenterology*, Vol. 53, No. 6, 1967, pp. 961-966.
	DC	Kaunitz, "Clinical uses of medium-chain triglycerides", *Drug Therapy*, Vol. 8, 1978, pp. 91-96.
	DD	Law et al., "The Effect of Dietary Protein Depletion on Immunocompetence: The Importance of Nutritional Repletion Prior to Immunologic Induction", *Ann. Surg.*, Vol. 179, No. 2, 1974, pp. 168-173.
	DE	Mahan et al., "The Assessment of Nutritional Status", *Krause's Food and Nutrition & Diet Therapy, 8th Edition*, Philadelphia: W.B. Saunders Company, 1992, pp. 293-313.
	DF	Mascioli et al., "Intravenous Infusion of a Physical Mixture of Medium and Long Chain Triglyceride Emulsion", *Clin. Res.*, Vol. 33, 1985, 275A.
	DG	Nichols et al., "Magnesium supplementation in protein-calorie malnutrition", *The American Journal of Clinical Nutrition*, Vol. 31, 1978, pp. 176-188.
	DH	Randall et al., "Randomized Clinical Trial in Hospitalized Patients Using Intravenous Medium Chain Triglyceride Emulsions", *Clin. Res.*, Vol. 33, 1985, 276A.
	DI	Sailer et al., "Medium Chain Triglycerides in Parenteral Nutrition" *Journal of Parenteral and Enteral Nutrition,* Vol. 5, No. 2, 1981, pp. 115-119.
	DJ	Simopoulos, "Omega-3 fatty acids in health and disease and in growth and development", *Am J Clin Nutr*, Vol. 54, 1991, pp. 438-63.
	DK	Sturman et al., "The Biology of Taurine in Nutrition and Development", *Adv. Nutr Res,* Vol. 3, 1980, pp. 231-299.
	DL	Sucher, "Medium Chain Triglycerides: A Review of Their Enteral Use in Clinical Nutrition", *Nutrition in Clinical Practice*, 1986, pp. 146-150.
	DM	Twyman et al., "High Protein Enteral Feedings: A Means of Achieving Positive Nitrogen Balance in Head Injured Patients", *Journal of Parenteral and Enteral Nutrition*, Vol. 9, No. 6, 1985, pp. 679-684.
	DN	
	DO	
	DP	
	DQ	
	DR	

Examiner	Date Considered 4/12/99

***EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.**

37 CFR 1.501
INFORMATION DISCLOSURE STATEMENT
IN A PATENT
(use several sheets if necessary)

Docket No. P97,1036	Serial No. 09/025,363
Applicant Mark et al.	
Filing Date February 18, 1998	Group Art Unit ~~1801~~ 1616

OTHER ART (Including Author, Title, Date, Pertinent Pages, Etc.)

	AA	Alexander et al., "Beneficial Effects of Aggressive Protein Feeding in Severely Burned Children", *Ann. Surg.*, Vol. 192, No. 4, 1980, pp. 505-517.
	AB	Anderson et al., "Intestinal Protein Loss During Enteral Alimentation in Critically Ill Patients", *J Parenter Enteral Nutr.*, Vol. 14 (Suppl), No. 1, 1990, pg. 24, Abstract.
	AC	August et al., "Determination of Zinc and Copper Absorption at Three Dietary Zn-Cu Ratios by Using Stable Isotope Methods in Young Adult and Elderly Subjects", *Am J Clin Nutr*, Vol. 50, 1989, pp. 1457-1463.
	AD	Austin, "Water: Guidelines for Nutritional Support", *Nutritional Support Services*, Vol. 6, No. 9, 1986, pp. 27-29.
	AE	Belcher et al., "Determinants of Urinary Nitrogen Excretion in Burned Patients", *Burns*, Vol. 14, No. 4, 1988, pp. 303-307.
	AF	Bjerve et al., "Alpha-Linolenic Acid Deficiency in Patients on Long-Term Gastric-Tube Feeding: Estimation of Linolenic Acid and Long-Chain Unsaturated n-3 Fatty Acid Requirement in Man", *Am J Clin Nutr*, Vol. 5, 1987, pp. 66-77.
	AG	Bogden et al., "Zinc and Immunocompetence in Elderly People: Effects of Zinc Supplementation for 3 Months", *Am J Clin Nutr*, Vol. 48, 1988, pp. 655-663.
	AH	Bogden et al., "Zinc and Immunocompetence in the Elderly: Baseline Data on Zinc Nutriture and Immunity in Unsupplemented Subjects", *Am J Clin Nutr*, Vol. 46, 1987, pp. 101-109.
	AI	Breslow, "Nutritional Status and Dietary Intake of Patients With Pressure Ulcers: Review of Research Literature 1943 to 1989", *Decubitus*, Vol. 4, No. 1, 1991, pp. 16-21.
	AJ	Brinson, "The Effect of Peptide-Based Diets on the Intestinal Microcirculation in a Rat Model", *Nutr Clin Prac*, Vol. 5, 1990, pp. 238-240.
	AK	Brinson et al., "Diarrhea Associated With Severe Hypoalbuminemia: A Comparison of a Peptide-Based Chemically Defined Diet and Standard Enteral Alimentation", *Critical Care Medicine*, Vol. 16, No. 2, 1988, pp. 130-136.
	AL	Brinson et al., "Intestinal Absorption of Peptide Enteral Formulas in Hypoproteinemic (Volume Expanded) Rats: A Paired Analysis", *Critical Care Medicine*, Vol. 17, No. 7, 1989, pp. 657-660.
	AM	Bynoe et al., "Nutrition Support in Trauma Patients", *Nutr Clin Prac*, Vol. 4, 1988, pp. 137-144.
	AN	Cerra et al., "Enteral Nutrition in Hypermetabolic Surgical Patients", *Critical Care Medicine*, Vol. 17, No. 7, 1989, pp. 619-622.
	AO	Cerra et al., "The Effect of Stress Level, Amino Acid Formula, and Nitrogen Dose on Nitrogen Retention in Traumatic and Septic Stress", *Ann. Surg.*, Vol. 205, No. 3, 1987, pp. 282-287.
	AP	Cerra et al., "What's New in Nutrition Support in Critical Care", *Perspective in Clinical Nutrition*, Kinney, Borum (Eds.), Urban & Schwarzenberg: Baltimore-Munich, 1989, pp. 323-338.

Examiner	Date Considered
	4/12/99

***EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.**

37 CFR 1.501
INFORMATION DISCLOSURE STATEMENT IN A PATENT
(use several sheets if necessary)

Docket No. P97,1036	Serial No. 09/025,363
Applicant Mark et al.	
Filing Date February 18, 1998	Group Art Unit ~~1801~~ 1616

OTHER ART (Including Author, Title, Date, Pertinent Pages, Etc.)

✓	BA	Chandra, "Trace Element Regulation of Immunity and Infection", *Journal of the American College of Nutrition*, Vol. 4, No. 1, 1985, pp. 5-16.
✓	BB	D'Atellis et al., "Branched-Chain Amino Acids", *Nutrition in Critical Care*, In Zaloga (ed.), St. Louis, MO: Mosby, 1994, pp. 81-106.
✓	BC	Dominioni et al., "Enteral Feeding in Burn Hypermetabolism: Nutritional and Metabolic Effects of Different Levels of Calorie and Protein Intake", *Journal of Parenteral and Enteral Nutrition*, Vol. 9, No. 3, 1985, pp. 269-279.
✓	BD	Dominioni et al., "Prevention of Severe Postburn Hypermetabolism and Catabolism by Immediate Intragastric Feeding", *J. Burn Care Rehab.*, Vol. 5, No. 2, 1984, pp. 106-112.
✓	BE	Ehrlich et al., "Effects of Cortisone and Vitamin A on Wound Healing", *Annals of Surgery*, Vol. 167, No. 3, 1968, pp. 324-328.
✓	BF	Ehrlich et al., "Effects of Vitamin A and Glucocorticoids upon Inflammation and Collagen Synthesis", *Ann. Surg.*, Vol. 177, No. 2, 1973, pp. 222-227.
✓	BG	Ehrlich et al., "Effects of Beta-Carotene, Vitamin A, and Glucocorticoids on Collagen Synthesis in Wounds", *Proc. Soc. Exp Biol Med.*, Vol. 137, No. 1, 1971, pp. 936-938.
✓	BH	Fabiani et al., "Oral Hyperalimentation in the Nutritional Management of Burned Patients", *SAMJ*, Vol. 67, 1985, pp. 768-770.
✓	BI	Freeman et al., "Effects of Magnesium Infusions on Magnesium and Nitrogen Balance During Parenteral Nutrition", *The Canadian Journal of Surgery*, Vol. 25, No. 5, 1982, pp. 570-574.
✓	BJ	Goodson et al., "Wound Healing", *Nutrition and Metabolism in Patient Care*, In: Kinney et al. (Eds.), Philadelphia, PA: WB Saunders, 1988, 635-642.
✓	BK	Gottschlich et al., "Enteral Nutrition in Patients with Burns or Trauma", *Clinical Nutrition Enteral and Tube Feeding 2nd Edition*, In: Rombeau et al. (Eds.), Philadelphia, PA: WB Saunders, 1990, pp. 306-324.
✓	BL	Gottschlich et al., "Vitamin Supplementation in the Patient with Burns", *J. Burn Care Rehab.*, Vol. 11, No. 3, 1990, pp. 275-279.
✓	BM	Granger et al., "Intestinal Absorption of Elemental and Standard Enteral Formulas in Hypoproteinemic (Volume Expanded) Rats", *Journal of Parenteral and Enteral Nutrition*, Vol. 12, No. 3, 1988, pp. 278-281.
✓	BN	Hadley et al., "Nutrition and Wound Healing", *Top Clin. Nutr.*, Vol. 5, No. 4, 1990, pp. 72-81.
✓	BO	Hallbook et al, "Serum-Zinc and Healing of Venous Leg Ulcers", *Lancet*, 1972, pp. 780-782.
✓	BP	Hunt, "Control of Wound Healing With Cortisone and Vitamin A", *The Ultrastructure of Collagen*, In: Longacre JJ (ed.), Springfield, IL: Charles C. Thomas, 1976, pp. 497-508.
✓	BQ	Hunt et al., "Effect of Vitamin A on Reversing the Inhibitory Effect of Cortisone on Healing of Open Wounds in Animals and Man", *Annals of Surgery*, Vol. 170, No. 4, 1969, pp. 633-641.
✓	BR	Hunt et al., "Selenium Depletion in Burn Patients", *Journal of Parenteral and Enteral Nutrition*, Vol. 8, No. 6, 1984, pp. 695-699.

Examiner	Date Considered
[signature]	4/12(55)/99

***EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next**

37 CFR 1.501 INFORMATION DISCLOSURE STATEMENT IN A PATENT (use several sheets if necessary)	Docket No. P97,1036	Serial No. 09/025,363
	Applicant Mark et al.	
	Filing Date February 18, 1998	Group Art Unit ~~1801~~ 1616

OTHER ART (Including Author, Title, Date, Pertinent Pages, Etc.)

✓	CA	Ireton-Jones et al., "Nutrition for Adult Burn Patients: A Review", *Nutr. Clin Prac.*, Vol. 6, No. 1, 1991, pp. 3-7.
✓	CB	Jahoor et al., "Dynamics of the Protein Metabolic Response to Burn Injury", *Metabolism*, Vol. 37, No. 4, 1988, pp. 330-337.
✓	CC	Johnson et al., "Metabolism of Medium-Chain Triglyceride Lipid Emulsion", *Nutrition International*, Vol. 2, No. 3, 1986, pp. 150-158.
✓	CD	Kissileff et al., "Physiology of the Control of Food Intake", *Ann. Rev. Nutr.*, Vol. 2, 1982, pp. 371-418.
✓	CE	Kubo et al., "Fluid and Electrolyte Problems of Tube-Fed Patients", *American Journal of Nursing*, Vol. 76, No. 6, 1976, pp. 912-916.
✓	CF	Levenson, "Micronutrients (Vitamins, Trace Minerals)", In ASPEN Program Manuel of Proceedings of The 16th Clinical Congress, 1992, pp. 189-198.
✓	CG	Long et al., "Metabolic Response to Injury and Illness: Estimation of Energy and Protein Needs from Indirect Calorimetry and Nitrogen Balance", *Journal of Parenteral and Enteral Nutrition*, Vol. 3, No. 6, 1979, pp. 452-456.
✓	CH	Mandt et al., "Nutritional Requirements", *Nutrition Support Handbook*, In: Teasley-Strausberg (ed.), Cincinnati, OH: Harvey Whitney Books Co., 1992, pp. 19-36.
✓	CI	McClave et al., "Immunonutrition and Enteral Hyperalimentation of Critically Ill Patients", *Digestive Diseases and Sciences*, Vol. 37, No. 8, 1992, pp. 1153-1161.
✓	CJ	Meredith et al., "Visceral Protein Levels in Trauma Patients Are Greater with Peptide Diet Than with Intact Protein Diet", *The Journal of Trauma*, Vol. 30, No. 7, 1990, pp. 825-829.
✓	CK	Ortiz et al., "A Comparative Post-Operative Study - An Enteral Solution Based on Free Amino Acids, *Gastroenterologic Clinique et Biologique*, Vol. 9, No. 2, 1985, pp. 182-183.
✓	CL	Pearson et al., "An Estimation of the Potassium Requirements For Equilibrium in Burned Patients", *Surgery Gynecology & Obstetrics*, Vol. 112, No. 3, 1961, pp. 263-273.
✓	CM	Pories et al., "Acceleration of Wound Healing in Man With Zinc Sulphate Given By Mouth", *Lancet*, 1967, pp121-124.
✓	CN	Prasad et al., "Serum Thymulin in Human Zinc Deficiency", *J. Clin. Invest.*, Vol. 82, 1988, pp. 1202-1210.
✓	CO	Ringsdorf et al., "Vitamin C and Human Wound Healing", *Oral Surgery*, Vol. 53, No. 3, 1982, pp. 231-236.
✓	CP	Ross et al., "Wound Healing and Collagen Formation - II. Fine Structure in Experimental Scurvy", *The Journal of Cell Biology*, Vol. 12, 1962, pp. 533-551.
✓	CQ	Ross et al., "Wound Healing and Collagen Formation - V. Quantitative Electron Microscope Radioautographic Observations of Proline-H^3 Utilization by Fibroblasts", *The Journal of Cell Biology*, Vol. 27, 1965, pp. 83-106.
✓	CR	Ross et al., "Vitamin A as a Hormone: Recent Advances in Understanding the Actions of Retinol, Retinoic Acid, and Beta Carotene", *Journal of The American Dietetic Association*, Vol. 93, No. 11, 1993, pp. 1285-1290.

Examiner	Date Considered
[signature]	4/12/99

***EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.**

37 CFR 1.501
INFORMATION DISCLOSURE STATEMENT
IN A PATENT
(use several sheets if necessary)

Docket No. P97,1036	Serial No. 09/025,363
Applicant Mark et al.	
Filing Date February 18, 1998	Group Art Unit ~~1801~~ 1616

OTHER ART (Including Author, Title, Date, Pertinent Pages, Etc.)

D	DA	Sandstead et al., "Zinc and Wound Healing: Effects of Zinc Deficiency and Zinc Supplementation", *The American Journal of Clinical Nutrition*, Vol. 23, No. 5, 1970, pp. 514-519.
D	DB	Silk, "Nutritional Support in Hospital Practice", Oxford, Blackwell Scientific Publications, 1983, pp. 79-82.
D	DC	Spiller et al., "Malabsorption", *Nutrition and Metabolism in Patient Care*, Kinney et al. (Eds.), Philadelphia, PA: WB Saunders, 1988, pp. 281-304.
D	DD	Stotts et al., "Nutrition: A Critical Component of Wound Healing", *AACN Clin Issues*, Vol. 1, No. 3, 1990, pp. 585-594.
D	DE	Szebeni et al., "Vitamin A Levels in the Serum of Burned Patients", *Burns*, Vol. 7, No. 5, 1981, pp. 313-318.
D	DF	Waxman et al., "Protein Loss Across Burn Wounds", *The Journal of Trauma*, Vol. 27, No. 2, 1987, pp. 136-140.
D	DG	Ziegler et al., "Efficiency of Enteral Nitrogen Support in Surgical Patients: Small Peptides v Non-Degraded Proteins", *Gut*, Vol. 31, 1990, pp. 1277-1283.
	DH	
	DI	
	DJ	
	DK	
	DL	
	DM	
	DN	
	DO	
	DP	
	DQ	
	DR	

Examiner SS/GH — Date Considered 4/12/99

***EXAMINER:** Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

Notice of References Cited

Application No.	Applicant(s)		
09/025,363	David Mark et al		
Examiner		Group Art Unit	Page 1 of 1
Shahnam Sharareh		1616	

U.S. PATENT DOCUMENTS

		DOCUMENT NO.	DATE	NAME	CLASS	SUBCLASS
	A	5,547,927	8/20/96	Cope et al	514	2
	B	5,480,872	1/2/96	Cope et al	514	21
	C	5,504,072	4/2/96	Schmidl et al	514	21
	D	5,700,782	12/23/97	Cope et al	514	21
	E					
	F					
	G					
	H					
	I					
	J					
	K					
	L					
	M					

FOREIGN PATENT DOCUMENTS

		DOCUMENT NO.	DATE	COUNTRY	NAME	CLASS	SUBCLASS
	N						
	O						
	P						
	Q						
	R						
	S						
	T						

NON-PATENT DOCUMENTS

		DOCUMENT (Including Author, Title, Source, and Pertinent Pages)	DATE
	U		
	V		
	W		
	X		

Exhibit C

UNITED STATES DEPARTMENT OF COMMERCE
Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
08/435,361	05/05/95	MAR	D P97,1038

EXAMINER	
SHARMEEN	
ART UNIT	**PAPER NUMBER**
1815	

MAILED
DEC 27 1995

MILL A SIMPSON
35TH FLOOR SEARS TOWER
233 SOUTH WACKER DRIVE
CHICAGO IL 60606

DATE MAILED: 12/27/95

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Advisory Action

Application No.	Applicant(s)
09/025,363	David Mark et al
Examiner	**Group Art Unit**
Shahnam Sharareh	1616

THE PERIOD FOR RESPONSE: [check only a) or b)]

a) ☐ expires _____ months from the mailing date of the final rejection.

b) ☒ expires either three months from the mailing date of the final rejection, or on the mailing date of this Advisory Action, whichever is later. In no event, however, will the statutory period for the response expire later than six months from the date of the final rejection.

Any extension of time must be obtained by filing a petition under 37 CFR 1.136(a), the proposed response and the appropriate fee. The date on which the response, the petition, and the fee have been filed is the date of the response and also the date for the purposes of determining the period of extension and the corresponding amount of the fee. Any extension fee pursuant to 37 CFR 1.17 will be calculated from the date of the originally set shortened statutory period for response or as set forth in b) above.

☐ Appellant's Brief is due two months from the date of the Notice of Appeal filed on _____ (or within any period for response set forth above, whichever is later). See 37 CFR 1.191(d) and 37 CFR 1.192(a).

Applicant's response to the final rejection, filed on *Sep 14, 1999* **has been considered with the following effect, but is NOT deemed to place the application in condition for allowance:**

☐ The proposed amendment(s):

☐ will be entered upon filing of a Notice of Appeal and an Appeal Brief.

☐ will not be entered because:

☐ they raise new issues that would require further consideration and/or search. (See note below).

☐ they raise the issue of new matter. (See note below).

☐ they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal.

☐ they present additional claims without cancelling a corresponding number of finally rejected claims.

NOTE: _____

☐ Applicant's response has overcome the following rejection(s): _____

☐ Newly proposed or amended claims _____ would be allowable if submitted in a separate, timely filed amendment cancelling the non-allowable claims.

☒ The affidavit, exhibit or request for reconsideration has been considered but does NOT place the application in condition for allowance because: SEE Attachment

☐ The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.

☒ For purposes of Appeal, the status of the claims is as follows (see attached written explanation, if any):

Claims allowed: _____

Claims objected to: _____

Claims rejected: *1-20*

☐ The proposed drawing correction filed on _____ ☐ has ☐ has not been approved by the Examiner.

☒ Note the attached Information Disclosure Statement(s), PTO-1449, Paper No(s). *7*.

☒ Other *see attached for response to arguements.*

Attachment to the Advisory Action

Claims 1-20 are pending.

Response to Applicants Arguments for Claim Rejections - 35 USC § 102

Applicant's arguments and the newly amended claims filed on December 3, 1999 have been fully considered but they are not found to be persuasive.

In contrary to Applicant's assertion that Schmidl et al does not anticipate the claimed invention, Examiner responds that Schmidl et al disclose suitable protein source including partially hydrolyzed protein (see col 4, lines 55-59.) and indicate the use of partially hydrolyzed protein or intact protein as the source of protein, not partially hydrolyzed protein and intact protein (see col 11 lines 31-34.) Further Schmidl's composition provides a non-protein calorie to grams of nitrogen ratio of ranging from 150:1 to 80:1 (see Col 5 lines 64-68 and Col 6 lines 1-11.) Applicant's argument that Schmidl's composition has caloric density of 1 Kcal/ml; not 1.4, is not impressive, because it inherently possess the claimed property. Schmidl et al disclose that their composition in the powder form has the caloric density of 4 cal/gram which can easily be diluted with an aqueous liquid or juice to yield the caloric density of 1.4 kcal/ml, while maintaining an osmolality of about 630-690 mosm/kg of water (see col 7 lines 50-59.) Thus, the rejection is proper and adhered to.

Response to Applicants Arguments for Claim Rejections - 35 USC § 103

Applicant's arguments and the newly amended claims filed on December 3, 1999 have been fully considered. Accordingly the rejections made under 35 USC § 103 in Paper no. 4, filed

on April 28, 1999 have been withdrawn. However, Applicant's arguments were not found persuasive in respect to the rejections made under 35 USC § 103 in Paper no. 6, filed on September 14, 1999 as being unpatentable over Schmidl et al US Patent 5,504,072 and Gray et al 5,714,472. In response to Applicant's argument Examiner replies that the test for obviousness is not whether the features of a secondary reference may be bodily incorporated into the structure of the primary reference; nor is it that the claimed invention must be expressly suggested in any one or all of the references. Rather, the test is what the combined teachings of the references would have suggested to those of ordinary skill in the art. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981). In the instant case, Schmidl et al teach the desired NPC:N ratio for critically ill patients to be in the range of 150:1 to 80:1 (see col 5 lines 65-67 and col 6 lines 1-3.) further it is well known in the art that the nitrogen content of the composition can be measured to best fit the needs of critically ill patients; as indicated by Schmidl et al (see col 6 lines 2-9.) Also the use of antioxidants, vitamins and various minerals is routine in nutrition art, and further Schmidl et al provide such teachings in their patent (see col 9 lines 45-66, col 10 lines 1-25.)

Gray et al teach an enteral nutritional formulation that meets the nutritional needs of critically ill and metabolically stressed patients such as post-surgical patients or patients suffering from trauma in an intensive care setting, therefore, one skilled artisan would have been motivated to change the nonprotein calorie to grams of nitrogen ratio of Gray's composition to the desired ratio best fit for critically ill patients; as taught by Schmidl et al, and modify Gray's composition to formulate a product that suit the needs of metabolically stressed patients.

For the above stated reasons, said claims are properly rejected under 35 U.S.C § 103, and therefore, the rejections are adhered to.

In response to Applicant's arguments that the amended claims in Paper No. 5, filed on July 19, 1999 did not necessitate the new ground of rejection, Examiner replies that the amended claims clearly change the scope of the original independent claims, thus Applicant's amendment necessitated new grounds of rejection and accordingly the action was made final. See MPEP 706.07(a).

All rejections that were not addressed in the final rejection are considered moot.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shahnam Sharareh, PharmD whose telephone number is (703) 306-5400.

sjs 12/21/99

SUPERVISORY PATENT EXAMINER

1616

37 CFR 1.501
INFORMATION DISCLOSURE STATEMENT
IN A PATENT
(use several sheets if necessary)

Docket No. P97,1036	Serial No. 09/025,363
Applicant Mark et al.	
Filing Date February 18, 1998	Group Art Unit 1616

U.S. PATENT DOCUMENTS

Examiner's Initials		Document Number	Date	Name	Class	Subclass	Filing Date If appropriate
✓	AA	4,112,123	09/05/78	Roberts	—	—	
✓	AB	5,221,668	06/22/93	Henningfield et al.	—	—	
✓	AC	5,340,603	08/23/94	Neylan et al.	—	—	
✓	AD	5,549,905	08/27/96	Mark et al.	—	—	
	AE						
	AF						
	AG						
	AH						
	AI						
	AJ						
	AK						

FOREIGN PATENT DOCUMENTS

		Document Number	Date	Country	Class	Subclass	Translation Yes	Translation No
✓	AL	0 721 742	07/17/96	Europe	—	—		
✓	AM	WO 97/16079	05/09/97	PCT	—	—		
	AN							
	AO							
	AP							

OTHER ART (Including Author, Title, Date, Pertinent Pages, Etc.)

	AQ	
	AR	
	AS	
	AT	

Examiner [signature] Date Considered 12/20/99

***EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.**

Exhibit D

Interview Summary

Application No.	Applicant(s)
09/025,363	David Mark et al
Examiner	**Group Art Unit**
Shahnam Sharareh	1616

All participants (applicant, applicant's representative, PTO personnel):

(1) *Shahnam Sharareh, Examiner* (3) _____

(2) *Robert Barrett, Applicant's Representative* (4) _____

Date of Interview *Jan 6, 2000*

Type: [X] Telephonic [ ] Personal (copy is given to [ ] applicant [ ] applicant's representative).

Exhibit shown or demonstration conducted: [ ] Yes [X] No. If yes, brief description:

Agreement [ ] was reached. [X] was not reached.

Claim(s) discussed: *1-20*

Identification of prior art discussed:
Schmidl et al US Patent 5,504,072

Description of the general nature of what was agreed to if an agreement was reached, or any other comments:
Mr. Barrett did not agree with the rejection under 102(b) as anticipated by Schmidl, because it does not disclose caloric density of 1.4 Kcal/ml. Mr. Barrett also requested clarification of standing rejections specifically which rejections are considered moot. In reply, Examiner clarifies that all rejections except those discussed in the Advisory Action, Paper No.9, are withdrawn. Accordingly claims 1-7, 9-13, 15, 17-20 stand rejected under 102(b) as anticpated by Schmidl, and claims 1-20 stand rejected under 103(a) as obvious over Schmidl and Gray. Further, the amendend claim 1 recites an enteral composition having a caloric density of at least 1.4 kcal/ml. There is no indication in the instant claims that the instant enteral composition is in the liquid form. Schmidl disclose enteral compositions that provide 3 to 4 kcal/gram in powder form or 1kcal/ml in liquid form (col 7 lines 33-60.) It is Examiner's position that Schmidl et al provides AT LEAST 1.4kcal/ml. Therefore, the claims stand rejected.

(A fuller description, if necessary, and a copy of the amendments, if available, which the examiner agreed would render the claims allowable must be attached. Also, where no copy of the amendents which would render the claims allowable is available, a summary thereof must be attached.)

1. [ ] It is not necessary for applicant to provide a separate record of the substance of the interview.

Unless the paragraph above has been checked to indicate to the contrary, A FORMAL WRITTEN RESPONSE TO THE LAST OFFICE ACTION IS NOT WAIVED AND MUST INCLUDE THE SUBSTANCE OF THE INTERVIEW. (See MPEP Section 713.04). If a response to the last Office action has already been filed, APPLICANT IS GIVEN ONE MONTH FROM THIS INTERVIEW DATE TO FILE A STATEMENT OF THE SUBSTANCE OF THE INTERVIEW.

2. [ ] Since the Examiner's interview summary above (including any attachments) reflects a complete response to each of the objections, rejections and requirements that may be present in the last Office action, and since the claims are now allowable, this completed form is considered to fulfill the response requirements of the last Office action. Applicant is not relieved from providing a separate record of the interview unless box 1 above is also checked.

Examiner Note: You must sign and stamp this form unless it is an attachment to a signed Office action.